

BROADENING REISSUE APPLICATION DECLARATION AND POWER OF ATTORNEY  
BY THE ASSIGNEE

I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I am authorized to act on for and on behalf of InterCorp Services Inc., which is the sole director and secretary of the Osmotica Corp. (Assignee), a corporation of the British Virgin Islands.

The entire right, title and interest in and to the patent identified below is vested in the Assignee.

Patentees: Joaquina Faour and Jorge E. Mayorga

Patent Number: 6,004,582

Issue Date: December 21, 1999

Title: Multi-layered Osmotic Device

I believe said patentees to be the original, first and joint inventors of the subject matter which is described and claimed in said patent, for which a reissue patent is sought on the invention entitled:

**"Multi-layered Osmotic Device"**

☒ the specification of which is attached hereto.

☐ the Specification of which was filed on \_\_\_\_\_ as Reissue Application Serial No. \_\_\_\_\_ and was amended on \_\_\_\_\_.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations § 1.56.

I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below:

1. by reason of the patentee claiming less than he/she had the right to claim in the patent.
2. by reason of the patentee failing to perfect the claim of priority in the patent.

At least one error upon which reissue is based is described as follows:

A) The patentee failed to claim:

- 24) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
  - a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having a preformed passageway

- therein, said semipermeable membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;
- c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and
  - d) an external coat comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.
- 25) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
  - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and
  - d) an external coat comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.
- 26) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
  - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall; and
  - d) an external coat comprising a second active agent for release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.
- 27) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
  - c) an inert, completely erodible or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall; and

- d) an external coat comprising a second active agent for immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.

Claim 24, as set forth above, is broader than claim 1 of the original patent in that claim 24 does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat.

Claim 25, as set forth above, is broader than claim 1 of the original patent in that claim 25 does not specify the physical properties of the semipermeable membrane since such physical properties are detailed in the specification. Claim 25 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. Subsection d) of claim 25 does not specify controlled delivery of the first active agent, since that is already specified in subsection a).

Claim 26, as set forth above, is broader than claim 1 of the original patent in that claim 26 does not specify the physical properties of the semipermeable membrane since such physical properties are detailed in the specification. Claim 26 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. Subsection c) of claim 26 also requires "at least one" preformed passageway in the wall. Subsection d) of claim 26 does not specify controlled delivery of the first active agent, since that is already specified in subsection a). Subsection d) also does not limit the release profile of the second active agent.

Claim 27, as set forth above, is broader than claim 1 of the original patent in that claim 27 does not specify the physical properties of the semipermeable membrane since such physical properties are detailed in the specification. Claim 27 also does not require the presence of the polymer poly(vinylpyrrolidone)-(vinyl acetate) in the inert completely erodible or water soluble polymer coat. Subsection c) of claim 27 also requires "at least one" preformed passageway in the wall. Subsection d) of claim 27 does not specify controlled delivery of the first active agent, since that is already specified in subsection a). Subsection d) also expands the release profile of the second active agent to include "immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent".

- B) During prosecution of the application underlying the original patent for which a reissue patent is sought, the patentee failed to provide a certified copy and verified translation of the priority Argentine patent application below and therefore failed to perfect the claim for priority in the original patent.
- C) At least one of the claims of the original patent contains language that might be confusing. In particular, in column 23, line 18 of claim 1, the term "drug" refers back to the term "first

active agent" in column 23, line 16, and in column 23, line 30 of claim 1, the term "drug" refers back to the term "second active agent" in column 23, line 29.

All errors corrected in this reissue application arose without any deceptive intention on the part of the applicant.

I hereby claim foreign priority rights under Title 35 U.S.C. §119 of any foreign application for patent or inventor's certificate on the invention listed below and have also identified below any foreign application for patent or inventor's certificate on the invention having a filing date before that of the application on which priority is claimed.

<u>P97 01 02351</u>	<u>May 30, 1997</u>	<u>Pending</u>
Application Serial No.	Filing Date	Status

I hereby appoint Rick Matos, Reg. No. 40,082, as agent with full power of substitution and revocation to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected therewith; and I request that all correspondence be directed to:

Rick Matos, Ph.D., Customer No.: 24,039  
 Innovar, L.L.C.  
 P.O. Box 250647  
 Plano, TX 75025-0647

that all calls be directed to (972) 747-7373; that all facsimile transmissions be directed to (972) 747-7375; and that all email messages be directed to [innovarllc@mindspring.com](mailto:innovarllc@mindspring.com).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon, or any patent to which this declaration is directed.




Date: November 19, 2001

Mr. Abdiel Mansfield  
 (for and on behalf of InterCorp Services Inc.,  
 which is sole director and secretary of  
 Osmotica Corp.)

Assignee's Address: Osmotica Corp.  
C/O Alfaro, Ferrer & Ramirez (BVI) Ltd.  
P.O. Box 915  
R. G. Hodge Plaza, Second Floor  
Upper Main Street  
Road Town

Tortola, British Virgin Islands

Full name of first inventor Joaquina Faour

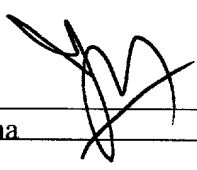
Inventor's signature 

Residence: Buenos Aires, Argentina

Citizenship Argentina

Post Office Address Ollereros 2312, 8°B, 1426 Buenos Aires, Argentina

Full name of second inventor Jorge E. Mayorga

Inventor's signature 

Residence: Buenos Aires, Argentina

Citizenship Argentina

Post Office Address Avda. Directorio 176, 4° Piso, 1424 Buenos Aires, Argentina